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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Anthony et al.		
Serial No.:	09/973,853	Case No.: 20757Y	Art Unit: 1624
Filed:	October 10, 2001		Examiner: Coleman, Brenda L.
For:	AZA- AND POLYAZA-NAPHTHALENYL CARBOXAMIDES USEFUL AS INTEGRASE INHIBITORS		

EXPRESS MAIL CERTIFICATE
DATE OF DEPOSIT August 16, 2004
EXPRESS MAIL NO. EL989934703US
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE" ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450.
MAILED BY: Mari Schepsis
DATE: August 16, 2004

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AFTER FINAL REJECTION

Sir:

This communication is in response to the Office Action mailed July 26, 2004, which set a three-month period for response that expires on October 26, 2004. Claims 1 and 3-37 are pending. Reconsideration is requested.

First Rejection under 35 U.S.C. § 112, first paragraph

Claims 26 and 30 remain rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the description. This rejection is traversed.

The Examiner is correct that claims 26 and 30 are directed to the inhibition of HIV integrase, and thus the mode of action of the claimed compounds is pertinent. However, it is first pointed out that, as disclosed in Example 193 of the subject application, representative examples of the claimed compounds are active in the HIV integrase strand transfer assay, which is strong evidence that the claimed compounds inhibit integrase. Furthermore, the Rule 132 Declaration by Dr. Daria Hazuda submitted with the amendment filed on May 6, 2004 presents compelling evidence that the claimed naphthyridine compounds (i) are *in vitro* and *in vivo* inhibitors of HIV replication whose mode of action is inhibition of integrase and (ii) are useful for inhibiting integrase. Since submission of the Hazuda Declaration, the studies discussed therein have published as Hazuda et al., *PNAS* 2004, 101 (11): 11233-11238 and Hazuda et al., *Science* 2004,

305: 528-532, copies of which are enclosed herewith. In view of this evidence, withdrawal of the rejection of claims 26 and 30 is requested.

Second Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 3-15, 25-27 and 32 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner has asserted that the term "N(H)R^t" in the definition of R^k in claim 1 constitutes new matter, citing in support Tronzo v. Biomet, 47 U.S.P.Q.2d 1829 (Fed. Cir. 1998). This rejection is traversed.

The written description requirement is satisfied if the application as originally filed allows the person of ordinary skill in the art to recognize that the inventor invented (i.e., had possession of) the subject matter now being claimed. See, e.g., Vas-Cath Inc. v. Mahurkar, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). Claim 4 as originally filed depends from claim 1 and accordingly incorporates by reference all the limitations set forth in claim 1. In original claim 4, the definition of R^k includes a saturated heterocyclic ring which is optionally substituted with, *inter alia*, N(R^a)R^t, wherein R^a is H or C_{1-4} alkyl. Original claim 7, which indirectly depends from claim 4 and thus also from claim 1, has an analogous definition. The person of ordinary skill in the art would recognize that the definition of R^k in claims 4 and 7 is inconsistent with the definition of R^k in original claim 1, which recites "N-heteromonocyclyl-N-C1-6 alkyl-amino-". The skilled artisan would understand that the inconsistency is due to the inadvertent omission of the appropriate antecedent in claim 1 (i.e., "N-heteromonocyclyl-NH-" which corresponds to N(H)R^t in pending claim 1), and thus would recognize that the Applicants were in possession of compounds of Formula I in claim 1 in which the definition of R^k includes the substituent N(H)R^t.

The Tronzo case cited by the Examiner merely stands for the proposition that later claimed generic subject matter does not comply with the written description requirement when there is no support for the later claimed matter in the original application. That is not the case here, because, as shown in the preceding paragraph, the original application does support the generic subject matter now being claimed.

Withdrawal of this rejection is requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 11 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner has asserted a lack of antecedent basis for -N(R^a)-C(=O)-CH_2)$_{1-2}$-C(=O)-N(R^a)$_2$ in the definition of R^k. This rejection is traversed, because it appears that the definition of R^k in claim 11 does not contain the term in question, although such a term does appear in the definition of Q^2. Furthermore, claim 11 is an independent claim and thus it is not seen how the term (whether in R^k or Q^2) lacks antecedent basis. In the event there is some aspect of this rejection

that Applicants fail to perceive, the Examiner is urged to telephone the undersigned to resolve it. Otherwise, withdrawal of the rejection is requested.

Provisional Obviousness-type Double Patenting Rejections

Claims 1, 3-15, 21-27, 30-32 and 37 have been provisionally rejected for obviousness-type double patenting over claims in each of the following copending applications:

A) U.S. Application No. 10/399,083 (Attorney Docket No. 20758YP).
B) U.S. Application No. 10/486,535 (Attorney Docket No. 20950Y).
C) U.S. Application No. 10/398,929 (Attorney Docket No. 20760YP).
D) U.S. Application No. 10/218,537 (Attorney Docket No. 20951Y).

In view of the foreging remarks on the section 112 rejections, it is believed that the application is in condition for allowance apart from the provisional double patenting rejections A to D. In accordance with paragraph I.B of MPEP § 804, it is requested that the provisional rejections be withdrawn in this application and that the application be permitted to issue.

The Examiner is asked to telephone the undersigned should any minor matters need to be resolved before a Notice of Allowance can be mailed.

Respectfully submitted,

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Date: August 16, 2004

Attachments (Hazuda et al. references)